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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,500	11/21/2003	Timothy B. Hibler	THIBL.001A	3027

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EXAMINER	
MENDOZA, MICHAEL G	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s) C	
	10/719,500	HIBLER, TIMOTHY B.	
	Examiner	Art Unit	
	Michael G. Mendoza	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-54* is/are rejected.

7)☒ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 November 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/10/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "the at least one expandable dilator is inserted through the hollow tube and expands the tube", the at least one expandable dilator comprises a series of successively larger dilators", "an optical imaging component in the elongated member", "the seal assembly is a dimpled balloon", and "a plurality of valves" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 11 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Specifications discloses an expandable dilator attached to the to a hollow tube. The Examiner was unable to find enabling disclose of an expandable dilator inserted through the hollow tube or wherein the dilator inserted through the tube comprises a series of successively larger dilators.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-10, 13-28, 31-39, 41, and 47-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Nobles et al. US 2002/0013601 A1.

5. As to claims 1-8, Nobles et al. teaches a cervical medical device, comprising: an elongated member; an expandable mechanism attached to the elongated member; an anchoring feature; wherein the anchoring feature is deployable component attached to the elongated member distally of the expandable mechanism; wherein the anchoring feature is an uneven outer surface of the expandable mechanism when it is expanded; wherein the expandable mechanism is a corrugated balloon; wherein the expandable mechanism is a ridged balloon; wherein the elongated member comprises a lumen running through a length of the device; wherein the anchoring feature and the expandable mechanism are independently inflatable balloons [0070]; wherein the anchoring feature is a series of spaced ridges along a length of the expandable mechanism.

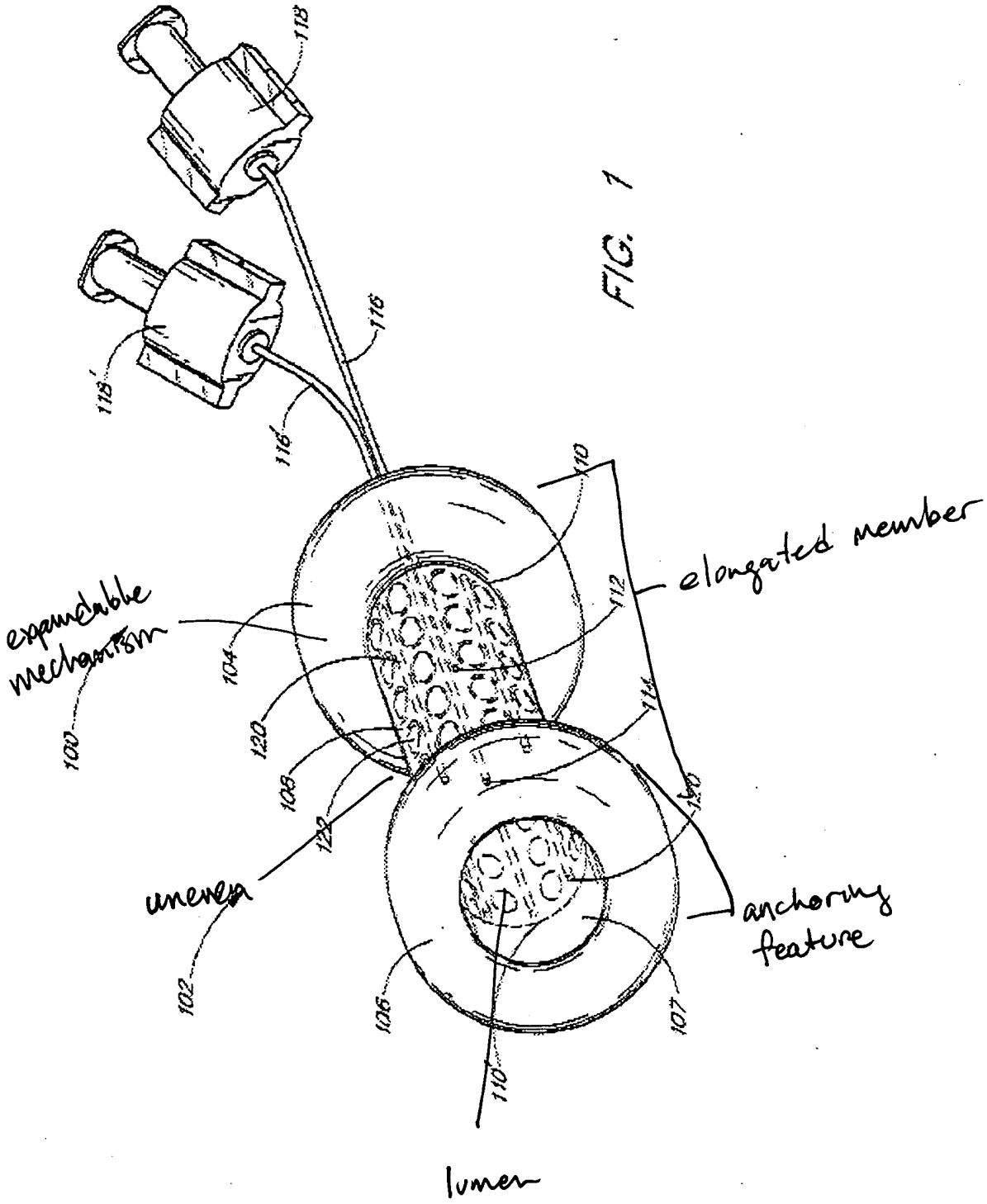

118'
118
116'
116
110
elongated member
112
expandable mechanism
104
100
120
114
108
120
122
anchoring feature
uneven
102
106
107
110
lumen

FIG. 1

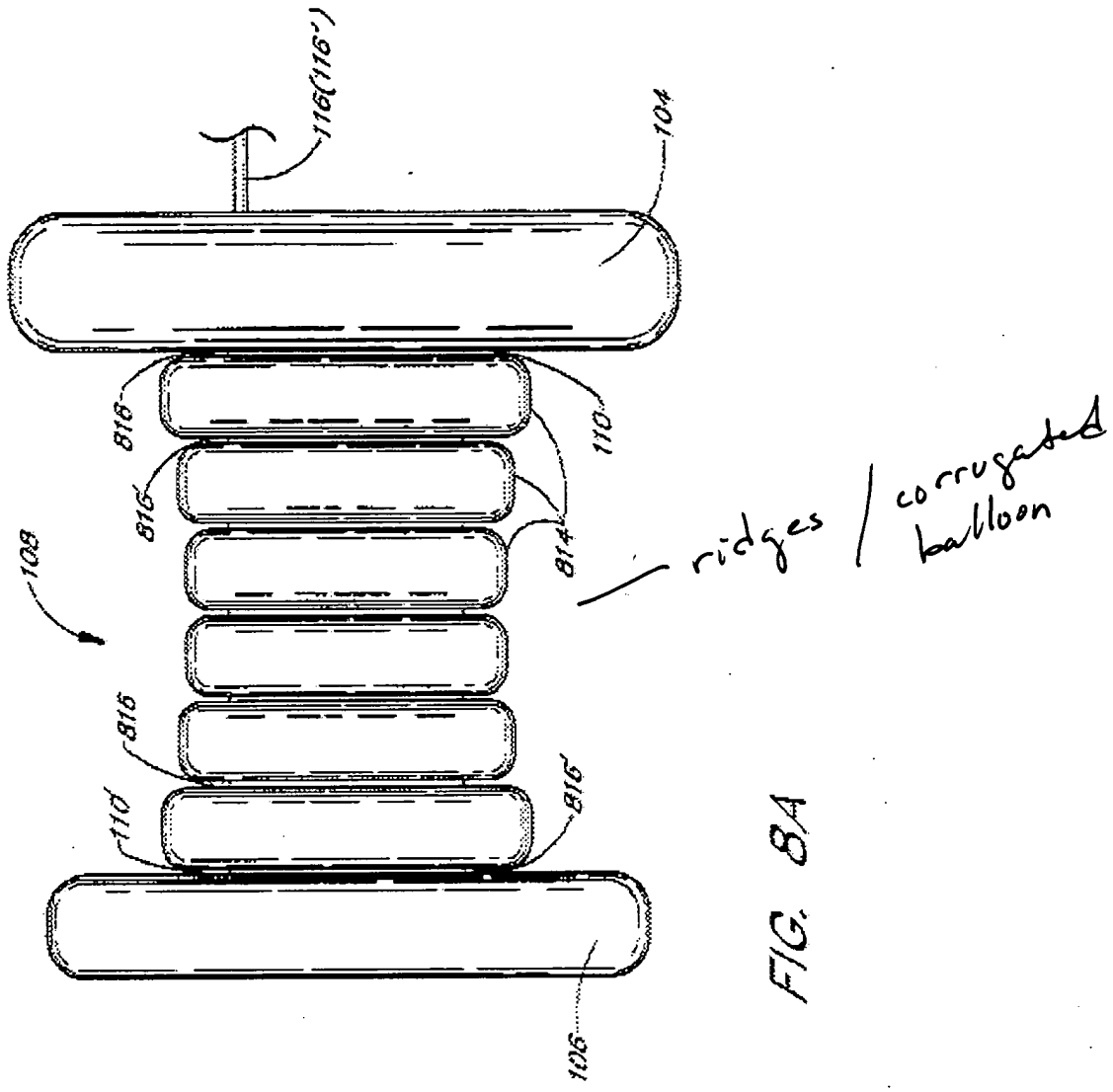
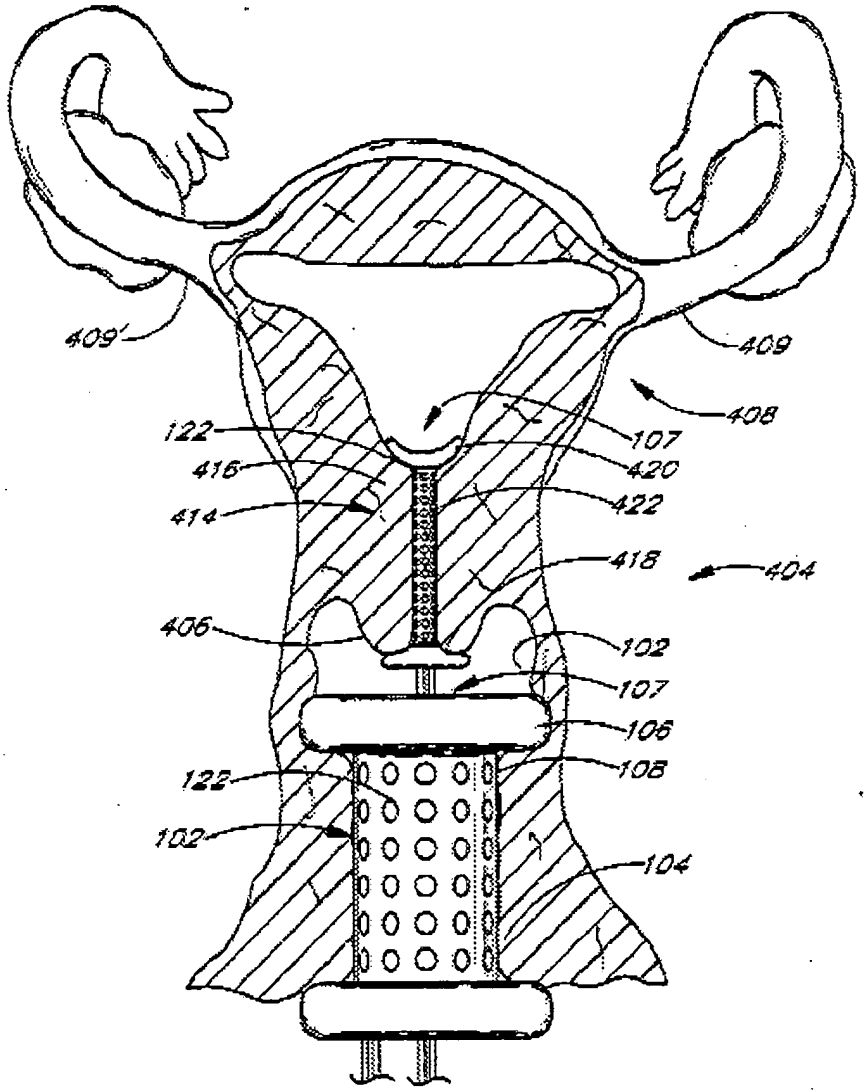


FIG. 8A

6. As to claims 9, 10, and 13-17, Nobles et al. teaches a cervical anchoring method, comprising: inserting a hollow tube into a cervical canal; inserting at least one expandable dilator into the cervical canal; radially expanding the at least one expandable dilator within the canal to dilate the cervical canal while the tube is in the canal; wherein the at least one expandable dilator is attached to the outer surface of the hollow tube; wherein the wherein the at least one expandable dilator has a corrugated outer surface; wherein the at least one expandable dilator has an uneven outer surface;

wherein the at least one expandable dilator has a ridged outer surface; wherein the at least one expandable dilator comprising a series of two balloons along the tube; wherein the series of two balloons comprises an anchor balloon distally of a dilating balloon.



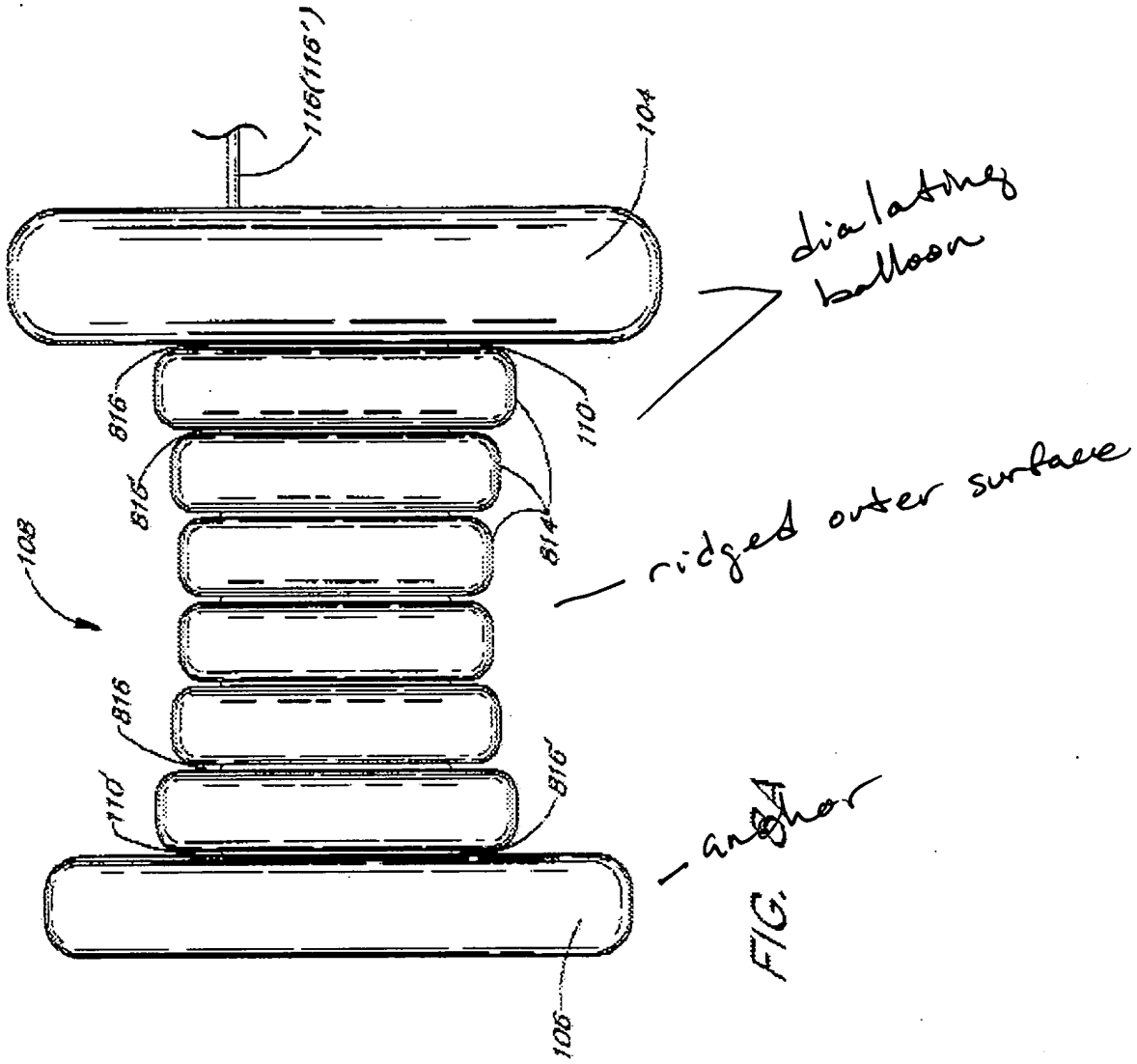


FIG. 8A

7. As to claims 18-28, Nobles et al. teaches a cervical dilating device, comprising: an elongated member having a proximal end and a distal end; a first expandable component attached to the distal end of the elongated member; a second expandable component attached to the elongated member proximally of the first expandable component; wherein the elongated member comprises a lumen running the entire length of the device; an expansion mechanism coupled to the first and second expandable components, wherein the expansion mechanism is a fluid-filled syringe;

wherein the expansion mechanism is a gas-filled syringe [0070]; wherein the first and second expandable components are inflatable balloons; wherein the first expandable component is a rounded balloon and the second expandable component is a cylindrical balloon; wherein the first and second expandable components are adjustable between a radially collapsed condition and a radially expanded condition (fig. 16A & 16B); an optical imaging component in the elongated member [0066]; and wherein the second expandable member has a length between 40 millimeters and 100 millimeters when expanded [0056].

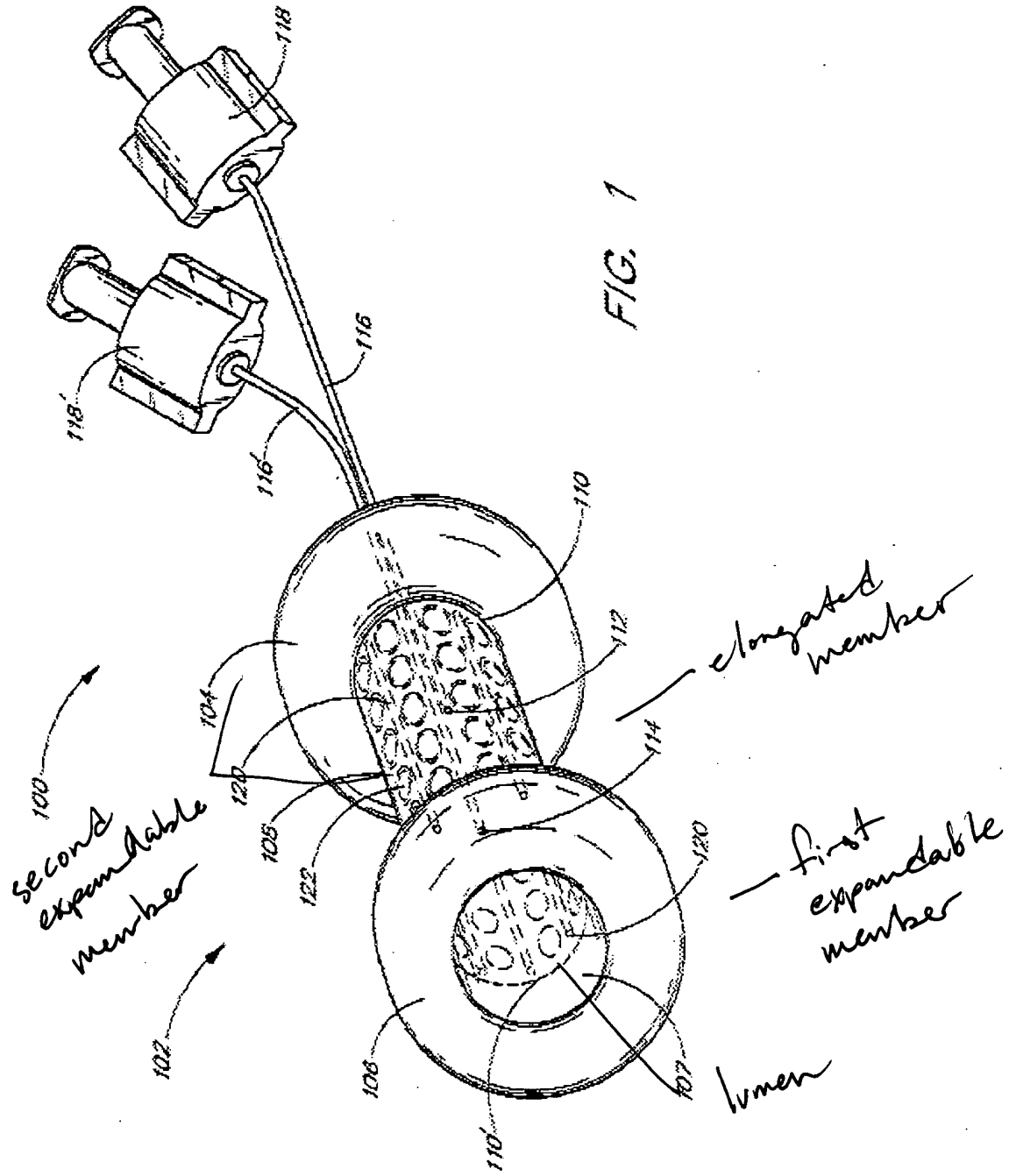


FIG. 1

8. As to claims 31-39 and 41, Nobles et al. teaches a cervical sealing device, comprising: an elongated member having a proximal end and a distal end; an expandable seal assembly attached to the elongated member, wherein the seal

assembly has an uneven surface in an expanded condition; wherein the elongated member comprises a lumen running through a length of the device; an expansion mechanism coupled to the seal assembly; wherein the expansion mechanism is a fluid-filled syringe; wherein the expansion device is a gas-filled syringe [0070]; wherein the seal assembly has a length between 40 millimeters and 100 millimeters when expanded [0056]; wherein the seal assembly has a diameter between 5 millimeters and 20 millimeters when expanded [0056]; wherein the seal assembly is a corrugated balloon; wherein the seal assembly is a balloon having a series of evenly spaced ridges along its length; wherein the seal assembly is a dimpled balloon.

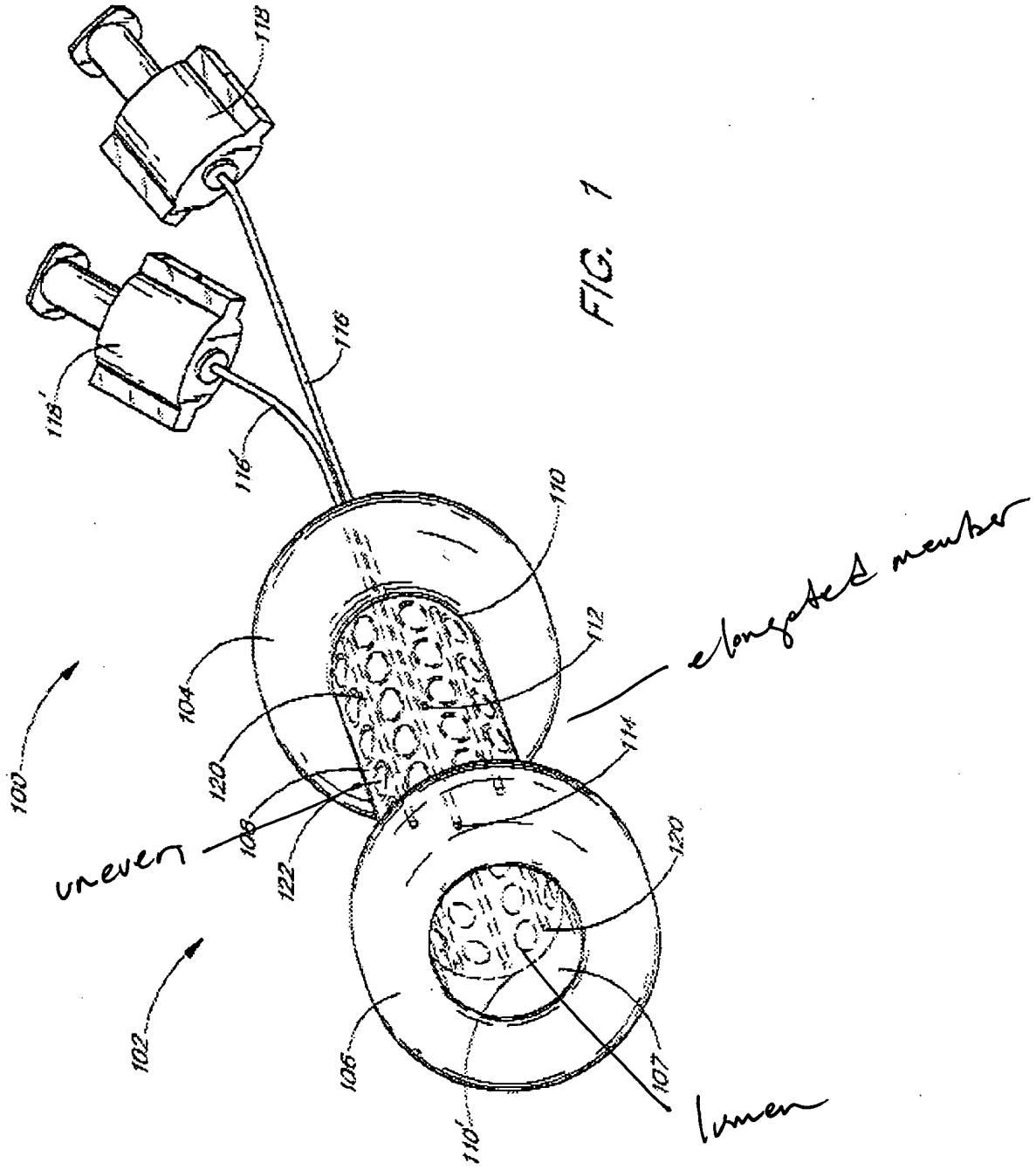

118'
118
116'
116
110
112
104
120
114
100
106
122
120
102
105
107
110'
elongated member
uneven
lumen

FIG. 1

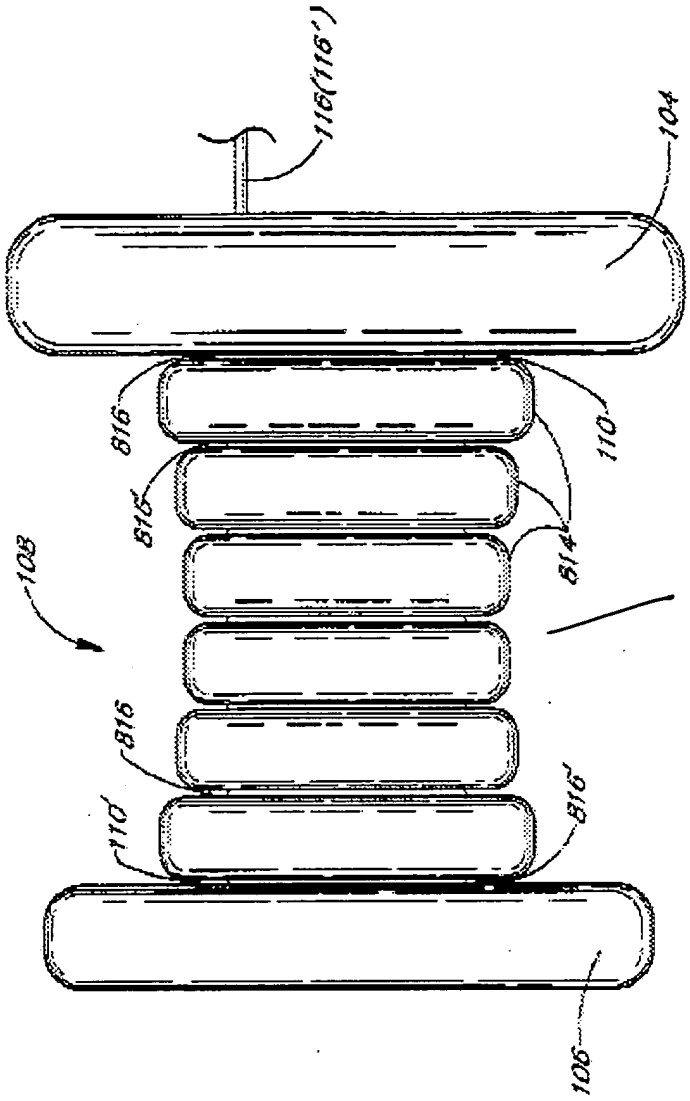


FIG. 8A

9. As to claims 47-51, Nobles et al. teaches a method of sealing a cervical canal, comprising: introducing a sealing device in the cervical canal, the device comprising a tube and an expandable seal assembly attached to the tube, wherein the seal assembly has an even surface when it is expanded; and expanding the seal assembly after introducing; wherein the device further comprises an expansion mechanism; wherein expanding comprises filling a balloon with a fluid [0070]; wherein the seal assembly is a

balloon having a series of spaced ridges along its length; and wherein the seal assembly is a corrugated balloon.

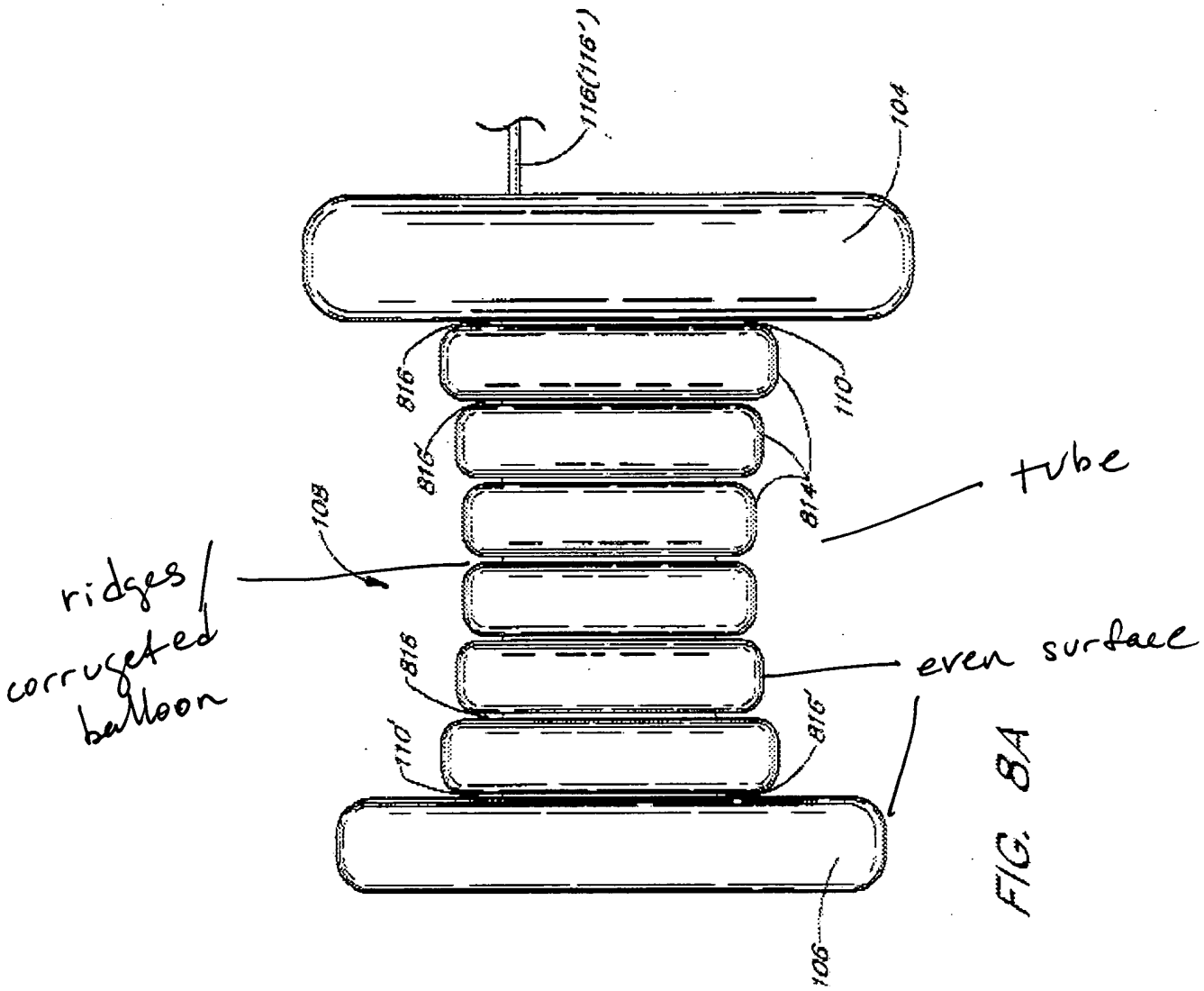
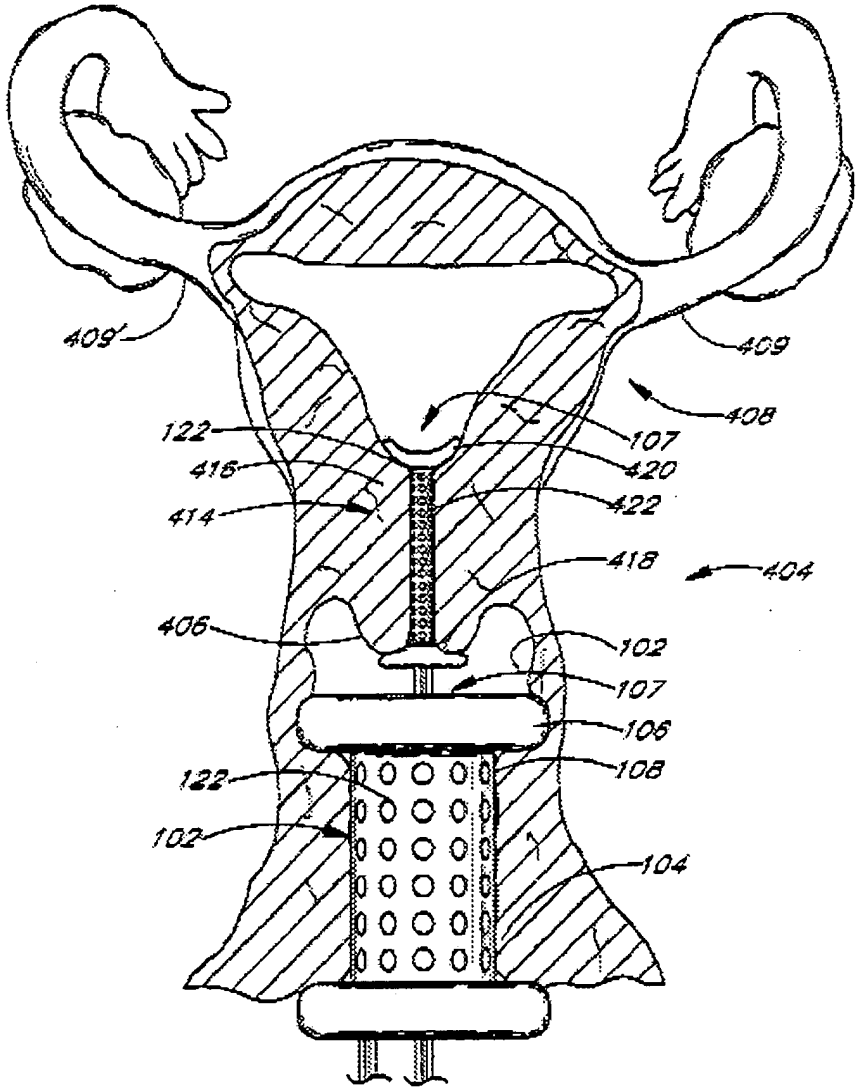


FIG. 8A

10. As to claims 52-54, Nobles et al. teaches a method of providing a seal for a cervical canal, comprising: inserting a cervical sealing device into the cervical canal, the device comprising a cannula (116 & 116') having a plurality of valves (118 & 118'), and a inflatable balloon attached to the cannula, wherein the balloon has an uneven surface when inflated; and inflating the balloon while the device is in the cervical canal

(fig. 4 & 4A); wherein the device further comprises an obturator; removing the obturator after the cannula is inserted (figs. 16-20B).



11. Claims 1, 2, 7, 18, 20-26, and 42-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Ghodsian 4664114.

12. As to claims 1, 2, and 7, Ghodsian teaches a cervical medical device, comprising: an elongated member; an expandable mechanism attached to the

elongated member; an anchoring feature; wherein the anchoring feature is deployable component attached to the elongated member distally of the expandable mechanism; and wherein the anchoring feature and the expandable mechanism are independently inflatable balloons.

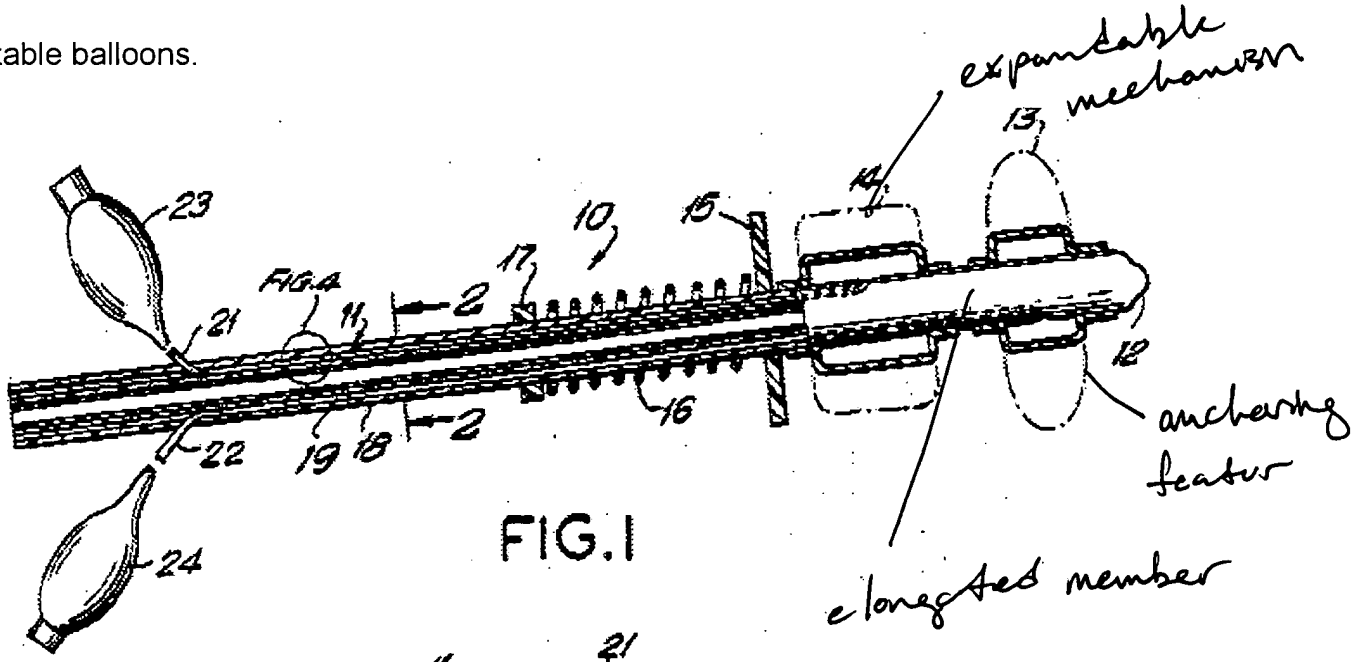


FIG.1

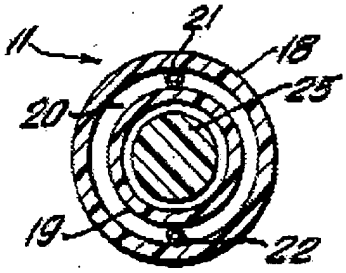


FIG.2

13. As to claims 18, 20-26, Ghodsian teaches a cervical dilating device, comprising: an elongated member having a proximal end and a distal end; a first expandable component attached to the distal end of the elongated member; a second expandable component attached to the elongated member proximally of the first expandable component; an expansion mechanism coupled to the first and second expandable components (23 & 24), wherein the expansion mechanism is a fluid-filled syringe;

wherein the expansion mechanism is a gas-filled syringe (col. 4, lines 47-49 & 58-62); wherein the first and second expandable components are inflatable balloons; wherein the first expandable component is a rounded balloon and the second expandable component is a cylindrical balloon; and wherein the first and second expandable components are adjustable between a radially collapsed condition and a radially expanded condition.

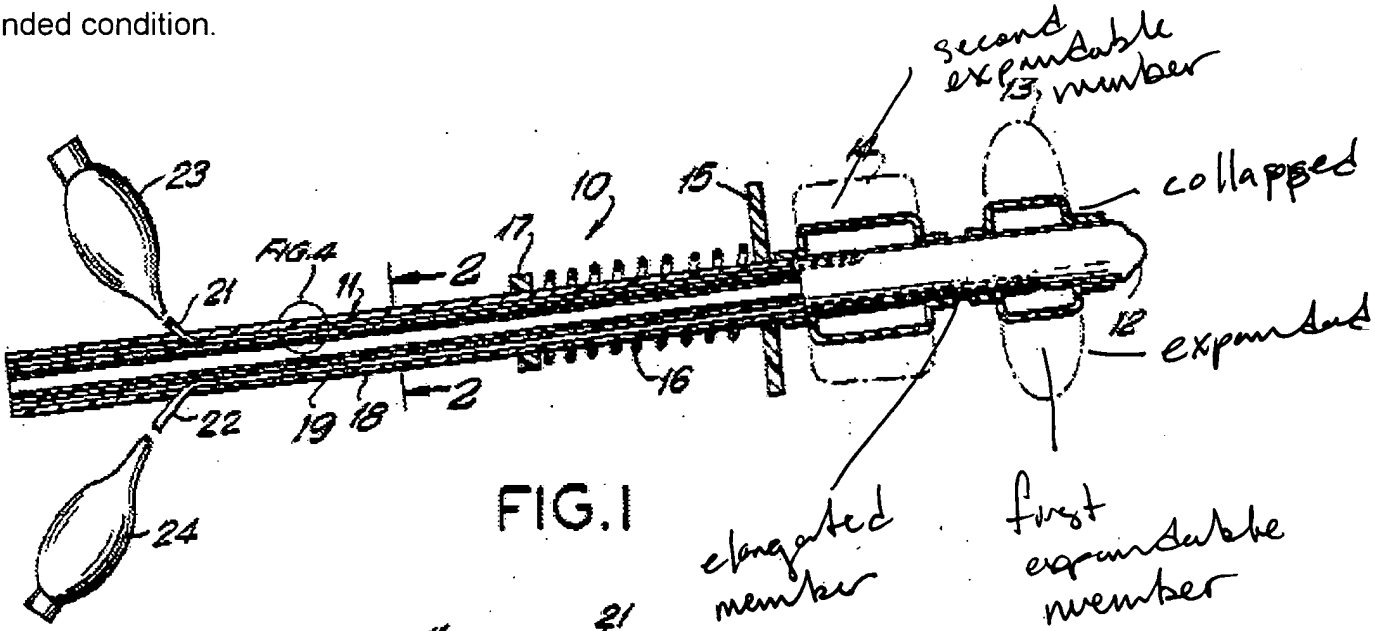


FIG.1

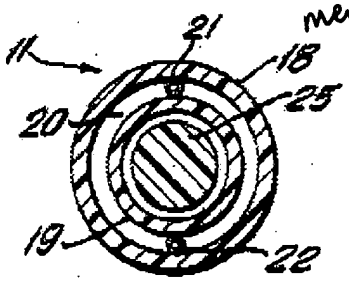


FIG.2

14. As to claims 42-46, Ghodsian teaches a method of dilating a cervical canal, comprising: inserting a dilating device into the cervical canal, the dilating device comprising an elongated member, a first expandable component attached to a distal end of the elongated member, and a second expandable component attached to the

elongated member proximally of the first expandable component; expanding the first expandable component; retracting the dilation device until resistance is felt while the first expandable component is expanded; and expanding the second expandable component in the cervical canal after retracting (col. 4, lines 39-65); wherein the device further comprises an expansion mechanism coupled to the first and second expandable components (23 & 24); wherein the first and second expandable components are expanded using a fluid-filled syringe coupled to the first and second expandable components; wherein the first and second expandable components are expanded using a gas-filled syringe coupled to the first and second expandable components (col. 4, lines 47-49 & 58-62); wherein the first and second expandable components are rigid-walled balloons.

15. As to claims 47-49, Ghodsian teaches a method of sealing a cervical canal, comprising: introducing a sealing device in the cervical canal, the device comprising a tube and an expandable seal assembly attached to the tube, wherein the seal assembly has an even surface when it is expanded; and expanding the seal assembly after introducing; wherein the device further comprises an expansion mechanism; and wherein expanding comprises filling a balloon with a fluid.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claims 29, 30, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nobles et al.

18. As to claims 29 and 30, Nobles et al. teaches the device of claim 18 except for the claimed diameter ranges of the second expandable member when expanded and collapsed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the claimed range limitations, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* USPQ 233. Furthermore, Nobles et al. teaches that the size of the apparatus is to be selected to conform to the anatomy of the surrounding tissue of the particular organ, lumen or body cavity [0054].

19. As to claim 40, Nobles teaches the device of claim 49 except for wherein the balloon has between 3 and 4 ridges. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the number of ridges as recited in the claim because the particulars of the number of ridges is a mere design choice obtained through routine observation and experimentation. Furthermore, the Applicant has not disclosed why the particulars of the dimensions are of importance or solve a stated problem or provide an advantage over the prior art.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-44963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MM

GLENN K. DAWSON
PRIMARY EXAMINER